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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,129	04/10/2006	Decpak Murpani	RLL-320US	2714

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EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/539,129	MURPANI ET AL.	
	Examiner	Art Unit	
	Melissa S. Mercier	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,7,9-13,16-27 and 45-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,7,9-13,16-27 and 45-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Claims 1-3, 6-7, 9-13, 16-27, and 45-49 are pending in this application. Applicant has canceled claims 4-5, 8, 14-15, and 28-44. Claims 1-3, 6-7, 9-13, 16-27, and 45-49 are rejected.

Priority

Applicants Claim of priority to PCT/IB03/06007 filed on December 16, 2003 is acknowledged.

Information Disclosure Statement

Receipt of the Information Disclosure Statement received on April 10, 2006 is acknowledged.

Claim Objections

Claims 2-3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Dependent claims can not dependent upon later recited claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 6-7, 9, 11-13, 17-26, 45, and 48-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Addicks et al. (US PG-Pub 2001/0043945).

Addicks discloses, "a pharmaceutical composition containing an admixture of phenytoin sodium and an erodible matrix which extends the release of the phenytoin sodium over about a two hour period. The erodible matrix comprises binder(s) and diluent(s) which control the release of drug from the pharmaceutical composition" (abstract). Binders are defined as compounds, which cause agglomeration of drug, and excipient particles during the manufacturing process and act to control the release of the drug from the dosage form. The agglomeration can be in the form of a powder. The dosage unit can be in the form of a capsule.

Regarding Claim 6, Addicks discloses "the amount of phenytoin sodium provided ranges from about 5% to about 90% per dosage unit" (paragraph 0017).

Regarding Claim 7, Addicks discloses, "the erodible matrix comprises about 1% to about 35% binder" (paragraph 0019).

Regarding Claims 9, 11-13 and 17-25, Addicks discloses, binders include "acacia, ethylcellulose, guar gum, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, hydroxyethylcellulose, starch, and hydrogenated vegetable oil" (paragraph 0013). The binders can be used in combination or alone. Additionally, diluents include "microcrystalline cellulose, powdered cellulose, lactose, starch, mannitol, dextrose, and dibasic calcium phosphate" (paragraph 0014). Lubricants including talc and magnesium stearate and glidants including talc and colloidal silicon dioxide, are disclosed (paragraph 0016).

Regarding Claims 45 and 48, phenytoin sodium is well known in the art for the treatment of epilepsy (paragraph 0003), therefore administration of the instantly claimed composition would inherently treat the symptoms of epilepsy, including generalized tonic-clonic and complex partial seizures.

Regarding Claims 2-3, 26, and 49, since the prior art teaches the same composition claimed in the instant claims; it would inherently meet the limitations of function as claimed in the above referenced claims. Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

Claims 1-3, 6-7, 9, 11-13, 17-19, 26-27 and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Straub et al. (US Patent 6,395,300).

Straub discloses a drug formulation comprising a low aqueous solubility drug provided in a porous matrix (abstract). Phenytoin sodium is disclosed as a suitable drug (column 5, line 44) and the drug matrix is in the form of powder (column 13, lines 29-31). Additionally, the matrices also may contain hydrophilic excipients such as water soluble polymers or sugars, wetting agents including acacia gum, surfactants, and tonicity agents" (Column 3, lines 50-53). Straub further teaches, "the porous drug matrix can be processed into capsules for oral administration" (column 3, lines 4-6).

Straub discloses the hydrophilic polymers can include "hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxyl-propylmethyl cellulose, and carboxymethyl cellulose" (column 8, lines 45-49).

Regarding Claims 2-3, 26 and 49, the prior art discloses the same composition as the instant claims. Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955). The recitation of "the matrix retains at least about 20%, 30%, or 60% at one hour" and the dissolution profile of the composition are considered function limitations. The USPTO does not have laboratory facilities in order to ascertain the functional limitations claimed.

Regarding Claim 6, "the porous drug matrix is at least 1-95% drug by weight" (column 3, lines 48-50).

Regarding Claim 7, Straub discloses, the amount of excipients in the drug matrix is less than 95% (column 8, lines 29-31). Straub defines excipients to include the hydrophilic polymers.

Regarding Claims 17-19, Straub discloses sugars such as "mannitol, dextrose and lactose" can be added to the drug matrix formulation (column 8, lines 58-65).

Regarding Claim 27, the selected drug is dissolved in an appropriate solvent; the drug solution is combined, typically under mixing conditions, with the pore forming agent or solution thereof. A solid pore forming agent can be added directly to the drug solution as solid particulates, preferably between about 100 nm and 10 um in size, to form a suspension of pore forming agent in the drug solution. Subsequently, further processing the resulting suspension, for example, using homogenization or sonication techniques known in the art, can reduce the solid pore forming agent particle size. Then, the solution, emulsion, or suspension is further processed to remove the drug solvent and the pore forming agent simultaneously or sequentially, using evaporation, spray drying, fluid bed drying, lyophilization, vacuum drying, or a combination of these techniques. The solvent and pore forming agents evaporate from the droplets into the drying gas to solidify the droplets, simultaneously forming pores throughout the solid. The solid (typically in a powder, particulate form) then is separated from the drying gas and collected" (column 11, line 47 to column 12, line 41). Since Straub discloses the dosage form can be in the form of capsules, it is the examiners position that capsules would be filled with the above resulting powder.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Straub et al. (US Patent 6,395,300) or in the alternative Addicks et al. (US PG-Pub 2001/0043945) in view of Pankhania et al. (US Patent 5,415,871).

The teachings of Straub and Addicks are discussed above and applied in the same manner.

Neither Straub nor Addicks disclose the use of xanthan gum or a combination of hydroxypropyl cellulose, hydroxypropyl methylcellulose and xanthan gum.

Pankhania discloses, "a sustained release pharmaceutical formulation comprising xanthan gum" (abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Straub's and Addicks' teachings with the teachings of Pankhania since Pankhania discloses, "the use of xanthan gum in the sustained release carrier generally allows a slower release of active ingredient into the body as compared to the use of naturally occurring hydrophilic gums. As a result, this provides the advantage that the proportion of sustained release carrier in the formulation may be reduced compared to most other sustained release formulations, thus enabling the sustained release formulation to be provided in a relatively small solid dosage form, if desired. As the proportion of sustained release carrier in the formulation is increased, the release of the active ingredient from the formulation is slowed" (column 3, lines 53-64).

One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success in making the extended release tablet, since the cited references all teach similar tablets.

Claims 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Addicks et al. (US PG-Pub 2001/0043945) in view of Jao et al. (US Patent 5,660,861).

The teachings of Addicks are discussed above and applied in the same manner.

Addicks does not disclose the use of additional pharmaceutical active agents.

Jao discloses "a dosage form for delivering an antiepileptic drug in a continuous release dose over time" (column 2, lines 61-64). Phenytoin sodium is discloses as a suitable drug (column 6, line 58).

Regarding Claim 45, phenytoin sodium is well known in the art for the treatment of epilepsy (column 6, lines 53-54), therefore administration of the instantly claimed composition would inherently treat the symptoms of epilepsy, including generalized tonic-clonic and complex partial seizures.

Regarding Claims 46-47, Jao discloses the use of "adjunctive antiepileptic drugs comprising phenytoin and phenobarbitone" (column 7, lines 14-16).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teaching of Addicks with the drug combination of Jao.

It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components

of drugs used for the treatment of epilepsy. It therefore follows that the instant claims define prime facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MSMercier

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